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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,861	04/10/2001	Albert Johan Pennings	10806-120	7399
24256	7590	05/27/2003		
DINSMORE & SHOHL, LLP 1900 CHEMED CENTER 255 EAST FIFTH STREET CINCINNATI, OH 45202			EXAMINER	
			SASTRI, SATYA B	
			ART UNIT	PAPER NUMBER
			1713	

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AG

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/829,861	PENNINGS ET AL.
	Examiner	Art Unit
	Satya B Sastri	1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 10 April 2001.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 30-42 is/are withdrawn from consideration.
- 5) Claim(s) 24 is/are allowed.
- 6) Claim(s) 1,3,4,8,12,14,27 and 28 is/are rejected.
- 7) Claim(s) 2,5-7,9-11,13,15-23,25,26 and 29 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10 April 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> .	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

1. This Office Action is in response to the correspondence dated April 1, 2003. Applicant's election of groups I and II with *claims 1-29* with poly(1-hydroxyl-1,3-propanediyl) as the elected species is acknowledged. Upon further consideration, examiner has rejoined groups I and II for examination. Group III with *claims 30-42* remains non-elected. Since the search with the elected species did not yield relevant prior art, search is extended to other non-elected species.

### *Specification*

2. The disclosure is objected to because of the following informalities:

- (a) Figure captions (1, 4-6) may need to include what EWC in the figures represents.
- (b) *Claim 19 and 20* includes a wrong dependency (on *claim 19*). The claim does not include a variable anywhere and therefore, it is unclear as to what R represents in *claims 19 and 20*.
- (c) *Claim 29* includes an "ophthalmic lens according to claim 27" where as *claim 27* refers only to an implant in the preamble.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. ***Claims 1, 8, 14, 27 and 28*** are rejected under 35 U.S.C. 102(b) as anticipated by Tahan (US 5,135,965).

The disclosure of Tahan is in regard to hydrogel forming polymers for contact lenses and intraocular lenses comprising hydrophilic monomer such as N-vinyl lactam, and a polyunsaturated polymeric cross-linking agent (abstract). The working examples 1 and 2 in columns 9 and 10 include the tensile strength and polymer and water content of the hydrated discs within the claimed range (***claims 1, 8, 14, 27 and 28***).

5. ***Claims 1, 3, 8, 14, 27, 28*** are rejected under 35 U.S.C. 102(e) as anticipated by Makabe et al. (US 6,262,208 B1).

The disclosure of Makabe et al. is in regard to ocular lens materials made from copolymers containing N-vinyl lactam, a fluorine containing unsaturated monomer, a hydrophilic

(meth)acrylamide and crosslinking agents. The ocular lenses are most suited as soft contact lens, intraocular lens, and artificial crystal lens (column 11, lines 30-32). The ocular lens materials have high water-retaining capability, excellent in transparency, mechanical strength etc. (abstract). More specifically, the ocular lenses have a water content of at least 50% by weight, a tensile strength of at least 150 kg/mm<sup>2</sup>, and a high light transmittance of at least 90% (column 11, lines 2-11, *claims 1, 3, 8, 14, 27, 28*).

6. *Claims 1, 3, 4, 8, 12, 14, 27, 28* are rejected under 35 U.S.C. 102(b) as anticipated by Ofstead (US 4,840,992).

The disclosure of Ofstead is in regard to copolymers of poly(vinyl alcohol) which can be hydrated to copolymers having controllably variable hydrogel properties and high strength. Such copolymers are particularly desirable as ophthalmic devices such as contact lenses, corneal implants and transplant, and intraocular lenses (abstract). The working examples and the properties of the polymers in Table III include water content and tensile strength within the claimed range (*claims 1, 3, 4, 8, 12, 14, 27 and 28*).

*Allowable Subject Matter*

7. *Claim 24* is allowable.

8. *Claims 2, 5, 6, 7, 9-11, 13, 15-23, 25, 26, 29* are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The present claims are allowable over the closest prior art based on Tahan (US 5,135,965), Makabe et al. (US 6,262,208 B1) and Ofstead (US 4,840,992). The prior art to Tahan and Makabe et al. do not teach hydrogels with specific properties or based on the polymers of the present invention (*claim 2, 5, 6, 7, 9-11, 13, 15-25*). Ofstead discloses hydrogels based on non-crosslinked poly(vinyl alcohol) but not on polymers disclosed in *claims 13, 22*. Additionally, the polyol polymer of the prior art does not include crosslinking through diisocyanate or epoxy compounds (*claims 15-18, 21, 23, 24, 25 and 26*) or modification of the hydrophilicity through the use of monoisocyanate compound (*claims 9-11*). Furthermore, the hydrogel according to this prior art does not have the properties disclosed in *claims 2, 5, 6 and 7* and therefore, the product based on such hydrogels (*claim 29*) is also allowable.

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satya Sastri at (703) 305-8490.

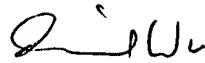
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached at (703) 308-2450.

Art Unit: 1713

Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist at (703) 308-2351.

SATYA SASTRI

May 22, 2003



DAVID W. WU  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700